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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,714	11/17/2000	Joseph H. Sklar	INNO-31	6629
7590 10/18/2004			EXAMINER	
Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02451-1914			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 10/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,714

Applicant(s)

HAYS ET AL.

Examiner

Bruce E Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-20 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-20, 28, 31 and 34 is/are allowed.
- 6) ☒ Claim(s) 2-3, 5-6, 8-9, 11-14, 26-27, 29-30, 32-33 is/are rejected.
- 7) ☒ Claim(s) 4 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Amendment***

Applicant's amendment, filed 8/13/04, to claim 13 claiming a tubular shank having a generally conically-shaped distal end has made the Examiner re-evaluate the claims previously indicated as being allowable. Tubular is defined as:

tu·bu·lar (t; ˈbye-lər, ty; ˈ-) *adjective*

1. Of or relating to a tube.
2. Constituting or consisting of tubes or a tube.
3. Shaped like a tube.¹

tube (t; b, ty; b) *noun*

1. **a.** A hollow cylinder, especially one that conveys a fluid or functions as a passage. **b.** An organic structure having the shape or function of a tube; a duct: *a bronchial tube*.
2. A small, flexible cylindrical container sealed at one end and having a screw cap at the other, for pigments, toothpaste, or other pastelike substances.
3. *Music*. The cylindrical part of a wind instrument.
4. *Electronics*. **a.** An electron tube. **b.** A vacuum tube.
5. *Botany*. The lower, cylindrical part of a gamopetalous corolla or a gamosepalous calyx.
6. *Chiefly British*. A subway; an underground.
7. A tunnel.
8. An inner tube.²

It is noted that the screw of Rieser et al as shown in figure 3 can be interpreted as being tubular. Applicant's use of the transitional phrase "comprising" allows for additionally elements such as the tube having a closed end 30, and the definition number 2 of "tube" allows for a closed end. It is noted that Rieser et al teaches the use of opening 14 which

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is applicable to the embodiment shown in figure 3. Additionally, a "tubular structure" does not have to have a cylindrical exterior and cylindrical interior.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 11, and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's disclosure fails to teach an elongated tubular shank having a generally conically-shaped distal end.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2, 5-6, 8, 11-14, 26, 29, 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Rieser et al (6,387,129).

Rieser et al teaches a fixation screw for fastening a graft ligament within a bone tunnel having a proximal end canted relative a longitudinal axis. See reasoning for canted end in column 4, lines 7-12. Said proximal end defines a generally planar end surface. Regarding the tubular limitation, the screw body has a hexagonal socket 28 forming a tubular body.

Regarding the limitation, "*the planar end surface is formed so that said outer periphery of said shank is concentric with a maximum outer diameter of said screw threads*" fails to define over the rejections. The Examiner notes that the claims only require the "planar end surface" to be a "**generally** planar end surface". Now referring to figures 3 and 4 of Rieser et al, the end surface includes a larger planar surface and a smaller surface which as shown appears to be a portion of a conical surface; referring to figure 3, the reference numeral 26 shows the intersection of the two surfaces. It is the Examiner's position that the two surface together form the "generally planar end surface"; therefore, the intersection of the two surfaces is clearly not the outer periphery

of the shank. Inherently the outer periphery of the shank at the generally planar end surface is concentric with a maximum outer diameter of the screw threads. Additionally, the Rieser's et al specification does not describe what the smaller surface is or does and might possible be a drawing error. One having ordinary skill in the art reading the teaching of Rieser et al on column 4, lines 7-12, would not conclude that shown in the drawings. It is the Examiner's position that this teaching alone (not including the drawings) fulfills the claim limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 9, 27, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riesser et al (6,387, 129) in view of Sutter et al (4,484,570).

Riesser et al teaches the screw as described above, however, is silent regarding apertures in the sidewall. Sutter et al teaches a screw having apertures 11e in the sidewall. It would have been obvious to one having ordinary skill in the art to have utilized the apertures of Sutter et al with the screw of Riesser et al such that bone material will grow into them which makes the screw become very stably anchored within the bone. See column 6, lines 29 et seq.

Allowable Subject Matter

Claims 4 and 10 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

Claims 15-20, 28, 31, and 34 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to read 'B. Snow', with a stylized flourish at the end.

BRUCE SNOW
PRIMARY EXAMINER